PMUSA Clinical Evaluation Clinical Process:
Documentation of cigarette consumption at MDSPS investigative sites

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For Confinement Periods:

1. The investigative site Pharmacy will document in the ClinQuick™ system each cigarette dispensed and each butt returned.

2. The daily consumption (cpd) will be calculated by summing the number smoked during the 24-h interval 07:00 to 07:00 or during the study-specific daily smoking interval (e.g., 07:00 to 23:00 for controlled smoking conditions).

For Ambulatory Periods:

1. At each subject visit, the investigative site Pharmacy will document in the EP-90™ system the number of full cigarette packs dispensed and the number of empty and partially full cigarette packs returned. Missing packs will be documented and the subject queried.

    a) Pharmacy-estimated (**MAXIMUM**) dispensed cigarettes per day (cpd) will be calculated as:

$$\frac{\text{(number of cigarettes dispensed) – (number of cigarettes returned at next visit)}}{\text{(number of days between dispensing and return)}}$$

2. The subject will document daily in the WatchPC™ device each cigarette (study or non-study) smoked and the time smoked.

    a) Subject-estimated (**MINIMUM**) daily consumption (cpd) will be calculated by summing the number smoked during each 24-h interval 07:00 to 07:00.

3. Both the maximum and minimum estimates of daily cigarette consumption at each study time point and the discrepancy between them will be calculated and presented in the clinical study report.

N.B.: *Each conventional carton contains 10 packs; each conventional pack contains 20 cigarettes. Deviations from this will be noted.*

Source: https://www.industrydocuments.ucsf.edu/docs/kgmj0001